CASE OT0426KQ3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Joseph A. Haslwanter et al.

Application No.: 09/940,784

Filed: August 28, 2001

For: NASAL SPRAY COMPOSITIONS

Examiner: S. Tran

Group Art Unit: 1615

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

REPLY BRIEF

In response to the Examiner's Answer that was mailed on October 3, 2003 for the subject application, the appellants are now addressing additional issues that have been asserted as affecting patentability of the appealed claims.

Claims 15-17 and 21-28 stand finally rejected under 35 U.S.C. § 103(a) as being rendered obvious by combination of teachings from U.S. Patent 4,728,509 to Shimizu et al., U.S. Patent 5,116,847 to Gilbert et al., and U.S. Patent 5,015,474 to Parnell. The cited documents contain the following teachings:

> The Shimizu et al. patent pertains to liquid pharmaceutical compositions that are eye drops or nasal drops, containing a particular anti-allergic drug substance that has a very low solubility in water. To create a solution formulation, it is asserted that the formulation must contain one of polyvinylpyrrolidone, a cyclodextrin, or caffeine, as a solubilizer ingredient. Examples of the patent showing preparations that contain polyvinylpyrrolidone indicate the average molecular weights as being 40,000 or 25,000, but there is nothing in the document that suggests using any mixture of polyvinylpyrrolidone products having different average molecular weights.

The Gilbert et al. patent discloses compositions containing the drug loperamide, including aqueous formulations that can be applied to nasal passages. Additional drug substances can optionally be included, such as the decongestant oxymetazoline hydrochloride. However, there is no mention of any need for certain of the ingredients required by the appellant's claims, such as polyvinylpyrrolidone.

The patent to Parnell describes moisturizing compositions that contain a natural oil, called "eriodictyon fluid." These compositions are said to be useful generally for treating dryness, and can be made suitable for oral, nasal, vaginal, or dermal applications. One embodiment (Example 12) is a liquid nasal formulation, optionally containing a decongestant, but there is no mention of polyvinylpyrrolidone possibly being present in this formulation.

The rejection appears to be based simply on a finding that all of the appellants' required ingredients are known in the art. However, there is no suggestion in the applied documents to make any combination of ingredients that will fully meet the limitations of the rejected claims. Appellants reiterate that in M.P.E.P. § 706.02(j) the requirements for a proper rejection under 35 U.S.C. § 103 are set forth, including the statement attributed to *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991): "Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

Absent the mention in any reference of record that the combination of two or more polyvinylpyrrolidone polymers having different average molecular weights, as required by the rejected claims, would be useful in a nasal spray composition, there simply can be no *prima facie* case for obviousness of Claims 15-17 and 21-28, and the improper rejection of those claims should not be sustained.

Claims 18-20 and 29-33 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over the above-discussed combination of patents, further including the teachings of E. Rybacki et al., "Auxiliary Substances in Technology of Drug Form," *Library of a Pharmacist, Volume 7*, Warsaw, 1980. The Rybacki et al. document discusses polyoxyethylene glycols, polyvinylpyrrolidone, and other substances, but does not predict any benefit from including two or more polyvinylpyrrolidones having different molecular weights in any type of composition. In addition, Rybacki et al. contains no teachings regarding any use for polyvinylpyrrolidones in aqueous nasal spray compositions.

The Examiner's Answer appears to assert that, since Rybacki et al. teach that various molecular weight range polyvinylpyrrolidone products are available, it would have been obvious to one having ordinary skill in the art to use two or more different molecular weight products to make the appellants' claimed nasal spray composition. This, however, is not in

accord with the M.P.E.P. discussion regarding the *Vaeck* decision, discussed above. No suggestion exists in the applied documents to make the specific combination that would lead to appellants' invention, and the rejection of claims 18-20 and 29-33 should not be sustained. In this regard, appellants further rely on the principle of *In re Freed*, 165 USPQ 570 (CCPA 1970) that a determination of obviousness must be based on facts, not on unsupported generalities, and on the principle expressed in *Ex parte Nesbit*, 25 USPQ2d 1817 (BPAI 1992) that it is necessary for the rejection to include a reason why one having ordinary skill in the art would have been led to make an asserted combination of teachings.

As the rejections do not have either technically or legally sufficient foundations, appellants continue to solicit their reversal on appeal.

Respectfully submitted,

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123

Attorney Docket No.: OT0426KQ3

AF/1615

PTO/SB/92 (08-03)
(Modified)

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